CLAIMS

We Claim:

1. A method, comprising:

a) providing a biological sample from a subject, said biological sample comprising genomic DNA;

b) detecting the presence or absence of DNA methylation in one or more genes to generate a methylation profile for said subject; and

c) comparing said methylation profile to one or more standard methylation profiles, wherein said standard methylation profiles are selected from the group consisting of methylation profiles of non cancerous samples and methylation profiles of cancerous samples.

2. The method of Claim 1, wherein said detecting the presence or absence of DNA methylation comprises the digestion of said genomic DNA with a methylation-sensitive restriction enzyme followed by multiplexed amplification of gene-specific DNA fragments with CpG islands.

3. A method of characterizing cancer, comprising:

a) providing a biological sample from a subject diagnosed with cancer, said biological sample comprising genomic DNA; and

b) detecting the presence or absence of DNA methylation in DAPK, GSTP, p15, MDR1, Progesterone Receptor, Calcitonin, RIZ, and RARbeta genes, thereby characterizing cancer in said subject.

4. The method of claim 3, further comprising the step of detecting the presence or absence of DNA methylation in one or more genes selected from the group consisting of S100, SRBC, BRCA, HIN1, Cyclin D2, TMS1, HIC-1, hMLH1E-cadherin, 14-3-3sigma, and MDGI.

5. The method of claim 3, wherein said characterizing cancer comprises detecting the presence or absence of chemotherapy resistant cancer.

6. The method of claim 5, wherein said chemotherapy is a nonsteroidal selective estrogen receptor modulator.

7. The method of claim 3, wherein said characterizing cancer comprises determining a chance of disease-free survival.

8. The method of claim 3, wherein said characterizing cancer comprises determining the risk of developing metastatic disease.

9. The method of claim 3, wherein said characterizing cancer comprises monitoring disease progression in said subject.

10. The method of claim 3, wherein said biological sample is a biopsy sample.

11. The method of claim 3, wherein said biological sample is a blood sample.

12. The method of claim 3, wherein said DNA methylation comprises CpG methylation.

13. The method of claim 3, wherein said detecting the presence or absence of DNA methylation comprises the digestion of said genomic DNA with a methylation-sensitive restriction enzyme followed by multiplexed amplification of gene-specific DNA fragments with CpG islands.

14. The method of claim 13, wherein said methylation-sensitive restriction enzyme comprises Hin6I.

15. The method of claim 3, wherein said cancer is breast cancer.

16. A kit for characterizing cancer, comprising reagents for detecting the presence or absence of DNA methylation in DAPK, GSTP, p15, MDR1, Progesterone Receptor, Calcitonin, RIZ, and RARbeta genes.

17. The kit of claim 16, further comprising reagents for detecting the presence or absence of DNA methylation one or more genes selected from the group consisting of S100, SRBC, BRCA, HIN1,Cyclin D2, TMS1, HIC-1, hMLH1, E-cadherin, 14-3-3sigma, and MDGI.

18. The kit of claim 16, further comprising instructions for using said kit for characterizing cancer in said subject.

19. The kit of Claim 18, wherein said instructions comprise instructions required by the United States Food and Drug Administration for use in *in vitro* diagnostic products.

20. The kit of claim 16, wherein said reagents comprise reagents for digestion of genomic DNA comprising said one or more genes with a methylation-sensitive restriction enzyme followed by multiplexed amplification of gene-specific DNA fragments with CpG islands.